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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,451	02/10/2005	Abdellah Tahri	TIP0043 USPCT	8852
27777	7590	03/16/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,451

Applicant(s)

TAHRI ET AL.

Examiner

Yong Chu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 02/078,384.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 3-9 are amended by amendment filed on February 21, 2006. Claims 10-11 are cancelled by amendment filed on February 21, 2006. Claims 12-19 are added by amendment filed on February 21, 2006. Therefore, claims 1-9, and 12-19 are currently pending in the instant application.

Information Disclosure Statement

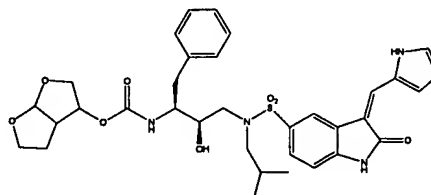
Applicant's Information Disclosure Statements, filed on 10 February 2005, have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

Priority

This application claims the benefit of European Patent Application EPO-02078384.1 filed on 14 August 2002 under 35 USC§119(a-d).

Response to Restriction

The response to the restriction request with provisionally election of Group I (e.g.



claims 1-6, 12 and 15 with species of Compound No.1

exemplified on page 39, Table 1) *with traverse* by Applicants' representative, Alana G.

Kriegsman dated on 21 February 2006, has been considered. Applicant's arguments on

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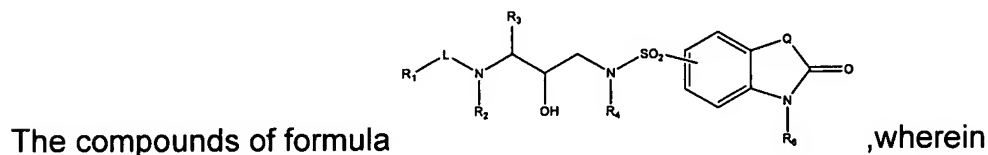
page 1 of Response have been fully considered but they are not persuasive. Please refer the previous office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

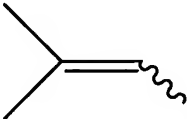
Status of the Claims

Claims 1-9, and 12-19 are pending in this application. Claims 7-9, 13-15, and 16-19 are withdrawn from further consideration by Applicants, as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and/or element and will require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other. Therefore, Claims 1-6, 12, and 16 are currently under examination.

The scope of the invention of the elected subject matter is as follows:



R₄ is H, or C₁₋₆alkyl;

Q represents  R_{5a} , and the rest substituents are defined as in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-6, 12, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional, which are chemically recognized to differ in structure and function. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Oath/Declaration

It does not identify properly the citizenship of each inventor. Abbreviation of the citizenship of each inventor "MA" or "BE" is not acceptable. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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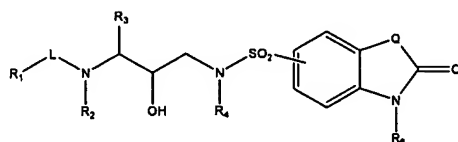
the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

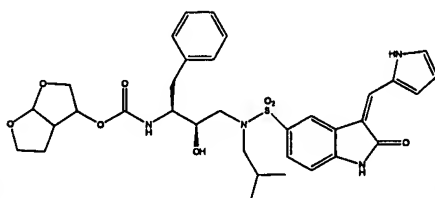
Claims 1-6, 12, and 16 are rejected under 35 U.S.C. 103 (a) as unpatentable over Erickson *et al.* WO 99/67254.

Applicants instant elected invention in claims 1-6, 12, and 16 teach a compound



having the formula

with a specific example of



compound

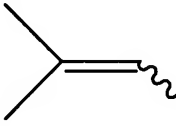
and their pharmaceutical composition,

wherein

R₁-R₃, and R₅-R₆ represents H, C₁₋₆alkyl, heterocyclic, etc.;

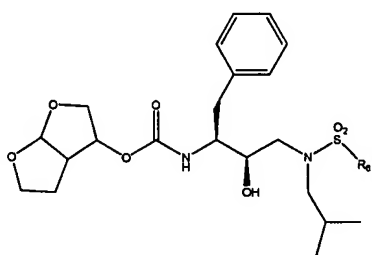
R₄ is H, or C₁₋₆alkyl;

L represents -C(=O)-, -O-C(=O)-, etc.;


Q represents R_{5a} ; and the rest substituents are defined as in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Erickson *et al.* WO 99/67254 teach a class of compounds with a general

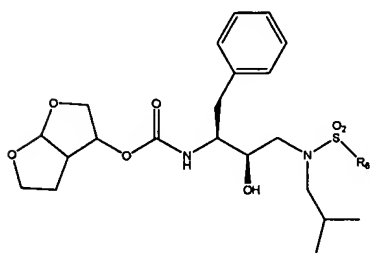


structure of wherein one of R_6 is an optionally substituted heteroaryl such as indole as defined on page 19 of the specification and a pharmaceutical composition which comprises the said compound as retroviral protease inhibitor.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Erickson *et al.* and the instantly claimed compounds is that they use exact the same compounds and compositions as retroviral protease inhibitors even though they have the same claimed scope.

Erickson *et al.* teach a class of compounds with formula



wherein one of R_6 is heteroaryl such as indole as defined on page 19 of the specification. However, Erickson *et al.* do not teach the exact compound

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with methylene substitutes in the current application, but point out the indole class of compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compounds prima facie obvious over the prior art, because the claimed compounds are alkylene substituted indoles as claimed in the prior art. The evidence over one compound for being unpatentable is held for the rest species in the group. The motivation to make the claimed compounds derives from the same expectation as retroviral protease inhibitors.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “combating” in claim 8 is indefinite because the specification does not clearly redefine the term. Deleting this term is suggested, since “treat” has been included in the claims 8.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The term "metabolite" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Deleting this term is suggested.

Conclusion

No claims are allowed.

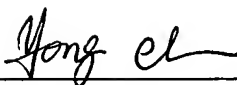
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

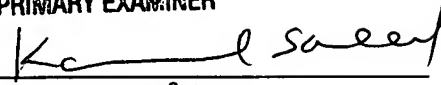
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER


for Joseph M. McKane
Supervisory Patent Examiner
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